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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,838	09/23/2005	Juli Yamashita	5703-010/NP	6048

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EXAMINER

CARLOS, ALVIN LEABRES

ART UNIT	PAPER NUMBER
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3714

MAIL DATE	DELIVERY MODE
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06/06/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/550,838	Applicant(s) YAMASHITA ET AL.	
	Examiner ALVIN L. CARLOS	Art Unit 3714	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 September 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/26/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The following is a Final Office action in response to communications received March 26, 2008. Claims 1-9 are now pending.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on March 26, 2008 was filed after the mailing date of the Non-Final office action on December 26, 2007. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-4, 8 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Kirikae 4209919.

Re claim 1, Kirikae teaches a replica comprising a thin bone part being reproduced with physical properties close to those of real tissue (column 1 lines 38-40). In addition, considering the thin bone part having a thickness of not more than 0.1 mm, since the general conditions of a claim are disclosed in the prior art, it is not inventive to

discover the optimum or workable ranges by routine experimentation.” **In re Aller, 220**

F.2d 454, 456, 105 USPQ 233, 235

Re claim 2, Kirikae teaches a replica comprising soft tissue being reproduced with physical properties close to those of real tissue (column 41-48).

Re claim 3, Kirikae teaches a part of replica is a breakable part that can be irreversibly broken during surgical manipulation (See figure 1, column 4 lines 22-32).

Re claim 4, Kirikae teaches a breakable part is replaceable (See figure 1 and 7, column 4 lines 33-39).

Re claim 8, Kirikae teaches a part of said replica is a breakable part that can be irreversibly broken during surgical manipulation (See figure 1, column 4 lines 22-32).

5. Claims 5-7, 9 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Kirikae 4209919 in view of Swaelens 5768134.

Re claim 5, Kirikae teaches the invention as discussed above.

However, Kirikae fails to teach the following limitations as taught by Swaelens: a production method for a replica (column 1 lines 7-14), comprising creating shape data concerning a thin bone part by CAD (column 4 lines 5-8), and rapid prototyping thin bone part on a basis of shape data, thereby reproducing a part of a human body (column 3 lines 64-67 and column 4 lines 1-3).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Kirikae’s invention in view of Swaelens in order to provide a method for making a medical model on the basis of digital image information of a body part

whereby the image information can be optimally used and can be put to use in practice as taught by Swaelens (column 2 lines 37-41).

In addition, considering the thin bone part having a thickness of not more than 0.1 mm, since the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” **In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235**

Re claim 6, Kirikae teaches the invention as discussed above. In addition, Kirikae teaches forming a resin coating on thin bone part (column 2 lines 14-18).

However, Kirikae fails to teach the following limitations as taught by Swaelens: rapid prototyping thin bone part (column 3 lines 64-67 and column 4 lines 1-3).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Kirikae's invention in view of Swaelens in order to provide a method for making a medical model on the basis of digital image information of a body part whereby the image information can be optimally used and can be put to use in practice as taught by Swaelens (column 2 lines 37-41).

Re claim 7, Kirikae teaches the invention as discussed above. In addition, Kirikae teaches a part of the human body is a paranasal sinus region (see figure 1, column 2 lines 41-43).

Re claim 9, Kirikae teaches the invention as discussed above. In addition, Kirikae teaches a part of the human body is a paranasal sinus region (see figure 1, column 2 lines 41-43).

Response to Arguments

6. Applicant's arguments filed March 26, 2008 have been fully considered but they are not persuasive.

7. In response to the applicants arguments that Kirikae does not teach a thin bone part having a thickness of not more than 0.1 mm. The Examiner disagrees. Kirikae teaches a model of a living body including a main body and organ components made of yieldable material (column 1 lines 41-44). It would have been obvious to one of ordinary skill in the art that Kirikae's model of a living body includes thin bone part in order to provide a user a feeling of reality as taught by Kirikae (column 1 lines 36-37).

Furthermore, considering the thin bone part thickness of not more than 0.1 mm, since the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum measurement ranges by routine experimentation. **In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235**

8. The Examiner reminds that it is the Applicant responsibility to read the entire disclosure of the prior art cited for rejections including the pertinent references cited.

9. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. **See In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).**

10. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. **See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).**

Conclusion

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALVIN L. CARLOS whose telephone number is (571)270-3077. The examiner can normally be reached on 7:30am-5:00pm EST Mon-Fri (alternate Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Xuan Thai can be reached on (571)272-7147. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Alvin L Carlos/
Examiner, Art Unit 3714
/XUAN M. THAI/
Supervisory Patent Examiner, Art Unit 3714